Expand your options

Enterra® Therapy

FOR CHRONIC NAUSEA AND VOMITING DUE TO GASTROPARESIS

enterra medical™

Your quest to help treat chronic intractable nausea and vomiting.

Chronic nausea and vomiting have been reported as the most bothersome symptoms of gastroparesis[1], a neuromuscular stomach disorder in which food empties from the stomach more slowly than normal.

Patients can experience serious disruptions in work, school, relationships, and social life.

There's no cure for gastroparesis but **Enterra® Therapy*** is an **advanced treatment option** that may help control the symptoms of chronic nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years.

*Humanitarian Device. Authorized by Federal law for use in the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. The effectiveness of this device for this use has not been demonstrated.

Enterra® Therapy is the only gastric electrical stimulation therapy that may help control chronic nausea and vomiting associated with gastroparesis.*

The Enterra Therapy System for Gastric Electrical Stimulation (GES) is indicated for the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years.

*Humanitarian Device. Authorized by Federal law for use in the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. The effectiveness of this device for this use has not been demonstrated. Enterra Therapy received Humanitarian Device Exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) in 2000.

More than

patients worldwide

have received Enterra Therapy to help resume everyday activities, like taking their seat back at the table.

Enterra Therapy does not work for everyone. Any combination of diet modification, medication, nutritional support, surgery, and Enterra Therapy may be necessary to control symptoms of gastroparesis.

Reduce vomiting frequency

Prospective randomized controlled clinical studies show that Enterra Therapy with Gastric Electrical Stimulation (GES) may significantly reduce vomiting frequency in patients with gastroparesis of idiopathic or diabetic origin.[2,3]

Improve quality of life

Prospective clinical studies show that Enterra Therapy may deliver significant improvement in health-related quality of life.[2,3]

Reversible

Unlike other surgical options, Enterra Therapy is reversible. The device can be turned off or removed.

ACG-recommended

The American College of Gastroenterology (ACG) Guideline for Management of Gastroparesis has a conditional recommendation, with moderate level of evidence, that GES may be considered for compassionate treatment in your patients with refractory symptoms, particularly nausea and vomiting due to gastroparesis.[4] A recommendation is graded "conditional" when there is uncertainty about the desirable effects of an intervention outweighing the undesirable effects.[2]

Contraindications

The Enterra Therapy System is not intended for patients whom the physician determines are not candidates for surgical procedures and/or anesthesia due to physical or mental health conditions. You cannot have diathermy (deep heat treatment from electromagnetic energy) if you have an Enterra device.

FDA-approved Humanitarian Use Device

Enterra Therapy is FDA approved to be safe and to have probable benefit for chronic intractable (drug refractory) nausea and vomiting due to gastroparesis of diabetic and idiopathic origin in patients aged 18-70 years.*

Risks

The Enterra System is MR Conditional. This means that patients with the Enterra System can safely have MRI examinations of some body parts under certain conditions. The conditions for MRI scans will vary with the type of MRI coil. Obtain the latest MRI guidelines by referring to the manuals at www.enterramedical.com/hcp/manuals. Enterra Therapy requires surgery and has risks, which may include infection, bleeding, bruising, and pain at the implant site. In addition to these risks, adverse events related to the Enterra System may include implant site pain, lead penetration, gastric or bowel obstruction or perforation, lead entanglement or erosion, irritation/inflammation over implant site and device mechanical or electrical problems. Any of these situations may require additional surgery or cause return of symptoms and some can be life threatening.

Studies demonstrate statistically significant improvements in quality of life for both diabetic[+] and idiopathic[++] patients[2,3]

Clinical evidence documenting the results of GES is found in prospective, controlled, multicenter studies.[2,3] Quality of Life (QoL) improvements are from baseline to 12 months.

[+] Device-related serious adverse events included lead migration/dislodgements (6.7%, 3/45), device migration (4.4%, 2/45), implant site hematoma (2.2%, 1/45), and implant site infection (2.2%, 1/45).

[++] Device-related serious adverse events included paresthesia (4.2%, 1/24), lead migration/dislodgement (4.2%, 1/24), and neurostimulator migration (4.2%, 1/24).

SIGNIFICANT REDUCTION IN **MEDIAN WEEKLY VOMITING** (AT 12 MONTHS)

68%
IMPROVEMENT

DIABETIC GROUP
(N = 36, P < 0.001)[2]

87%*
IMPROVEMENT

IDIOPATHIC GROUP
(N = 18, P < 0.001)[3]

SIGNIFICANT REDUCTION IN **HOSPITAL DAYS** (AT 12 MONTHS)

75%
IMPROVEMENT

DIABETIC GROUP
40 days to 10 days
(N = 39, P < 0.001)[2]

100%*
IMPROVEMENT

IDIOPATHIC GROUP
2 days to 0 days
(N = 19, P < 0.006)[3]

*The double-blind 3-month periods showed a non-significant reduction in vomiting in the ON vs. OFF period, the primary outcome variable
Manufacturer Sponsored Studies

Propensity to reduce the need for special feeding methods such as enteral and parenteral nutrition was observed in open label studies.[4]

Unlike other surgical options, Enterra Therapy is reversible.

How Enterra Therapy Works

A small, battery-powered gastric neurostimulator is implanted beneath the skin in the lower abdominal region. Leads deliver mild, controlled electrical pulses to the antrum portion of the stomach muscle wall. The system is programmed to optimize therapy for the individual patient.

Unlike other surgical options, therapy with gastric electrical stimulation is reversible. Using the external clinician programmer, therapy can be turned on and off at any time without surgery. The device can also be removed from the body.

Enterra II Neurostimulator

Battery-powered neurostimulator

Leads deliver mild, controlled electrical pulses to the antrum portion of the stomach muscle wall. The system is programmed to optimise therapy for the individual patient.

Using the external clinician programmer, therapy can be turned on and off at any time without surgery. The device can also be removed from the body.

Leads

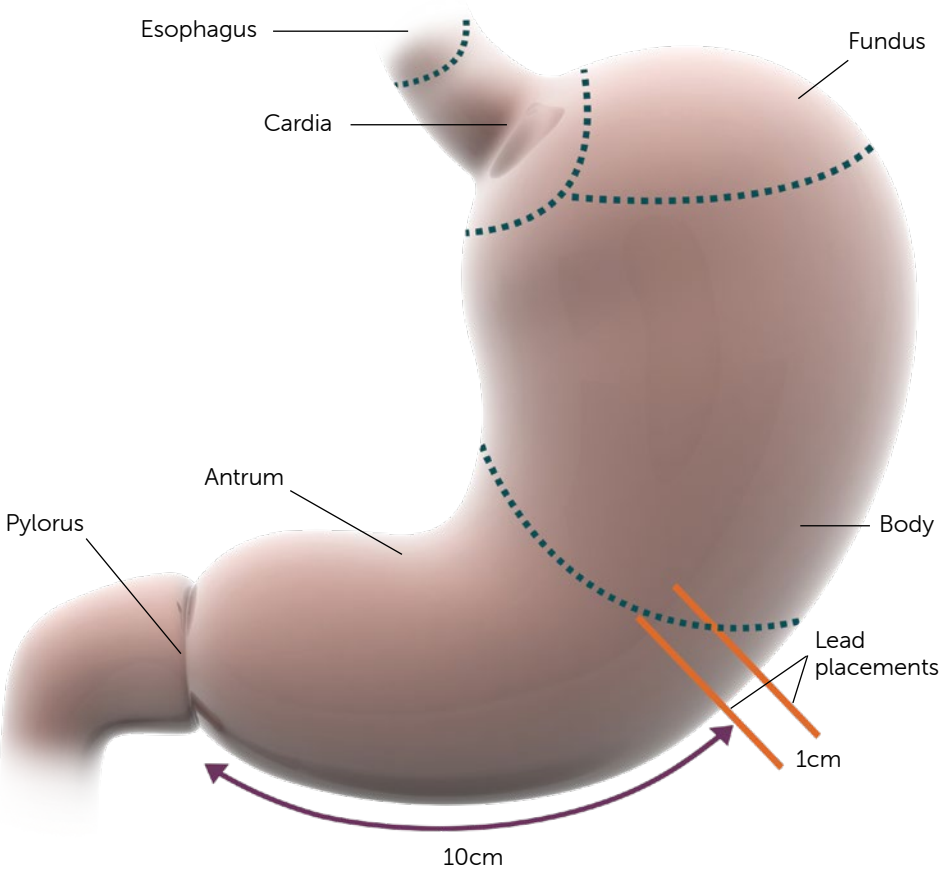
Two intramuscular leads

Implanted in the muscle wall of the stomach and connected to the neurostimulator

Programmer

External programmer

Used to noninvasively adjust patient therapy



The Enterra System is MR Conditional. This means that patients with the Enterra System can safely have MRI examinations of some body parts under certain conditions. The conditions for MRI scans will vary with the type of MRI coil. Obtain the latest MRI guidelines by referring to the manuals at www.enterramedical.com/hcp/manuals.

Enterra Therapy requires surgery and has risks, which may include infection, bleeding, bruising, and pain at the implant site. In addition to these risks, adverse events related to the Enterra System may include implant site pain, lead penetration, gastric or bowel obstruction or perforation, lead entanglement or erosion, irritation/inflammation over implant site and device mechanical or electrical problems. Any of these situations may require additional surgery or cause return of symptoms and some can be life threatening. For additional safety information, please refer to Indications, Safety, and Warnings at www.enterramedical.com/hcp/important-safety-information-for-healthcare-providers/.

AN INNOVATIVE APPROACH THAT MAY HELP CONTROL THE SYMPTOMS OF CHRONIC INTRACTABLE NAUSEA AND VOMITING DUE TO GASTROPARESIS.*

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To learn more about Enterra Therapy talk to your Enterra Medical representative or visit **www.enterramedical.com/hcp/**

The FDA approved the Humanitarian Device Exemption for Enterra Therapy in 2000. In 2022, Enterra Medical assumed commercial responsibility of Enterra Therapy.

Enterra Medical is dedicated to helping more people with chronic gastroparesis live better lives through advancing technology, bolstering clinical science, and accelerating patient access to Enterra Therapy.

1. Soykan I, Sivri B, Sarosiek I, et al. Demography, clinical characteristics, psychological and abuse profile, treatment and long-term follow-up of patients with gastroparesis. *Dig Dis Sci.* 1998;43:2398-2404.
2. McCallum RW, Snape W, Brody F, Wo J, Parkman HP, Nowak T. Gastric electrical stimulation with Enterra Therapy improves symptoms from diabetic gastroparesis in a prospective study. *Clin Gastroenterol Hepatol.* 2010;8:947-954.
3. McCallum RW, Sarosiek I, Parkman HP, Snape W, Brody F, et al. Gastric electrical stimulation with Enterra Therapy improves symptoms of idiopathic gastroparesis. *Neurogastroenterol Motil.* 2013;25(10):815-e636.
4. Camilleri M, Parkman HP, Shafi MA, Abell TL, Gerson L. Clinical Guideline: Management of Gastroparesis. *Am J Gastroenterol.* 2013;108:18-37.

Important Safety Information
Enterra® Therapy for treatment of chronic, resistant to medication nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years: patients should always discuss potential risks and benefits of the device with their physician. **Indications for Use:** The Enterra Therapy System for gastric electrical stimulation is indicated for use in the treatment of chronic, intractable (drug refractory) nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years.**Contraindications:** The Enterra Therapy System is not intended for patients whom the physician determines are not candidates for surgical procedures and/or anesthesia due to physical or mental health conditions. You cannot have diathermy (deep heat treatment from electromagnetic energy) if you have an Enterra device. **Warnings/Precautions/Adverse Events:** This system has not been evaluated for pregnant women, for use in patients under the age of 18, or patients over the age of 70. The system may be affected by or adversely affect cardiac devices. Strong sources of electromagnetic interference (EMI) such as from electrocautery, defibrillation/cardioversion, therapeutic ultrasound, radiofrequency (RF)/microwave ablation, or MRI, can result in serious injury, system damage, or operational changes to the system. EMI, postural changes, or other activities may cause shocking or jolting sensations.

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Humanitarian Device: Authorized by Federal law for use in the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. The effectiveness of this device for this use has not been demonstrated.

For further information, please contact Enterra Medical at info@enterramedical.com.
USA Rx only.

www.enterramedical.com

MKT-B-0002, Rev B

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